

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of Preterm Labor Rate in using Proloton and Vaginal Suppository Progesterone in High Risk Pregnancies

#### Protocol summary

z.sabokro@umsha.ac.ir

##### Summary

Background and aim: preterm birth is the leading cause of perinatal morbidity and mortality worldwide. The administration of progesterone and related compounds has been purposed as a strategy to prevent preterm birth. The objective of this trial was to determine comparison of preterm labor rate in high risk women for preterm labor who used 17- $\alpha$ -OH-p (porloton) IM and vaginal suppository progesterone. We used a randomized single blind study that included 100 high risk pregnancies for preterm labor (history of PTL, recurrent abortion , .....). Women were randomly assigned in two groups who used 17- $\alpha$ -OH-p (proloton) IM weekly or 100 mg of vaginal suppository for two weeks.

##### Recruitment status

**Recruitment complete**

##### Funding source

Hamadan university of medical sciences

##### Expected recruitment start date

2008-03-20, 1387/01/01

##### Expected recruitment end date

2011-01-02, 1389/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012155401N1**

Registration date: **2011-12-03, 1390/09/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-12-03, 1390/09/12

##### Registrant information

###### Name

Zahara Sabokro

###### Name of organization / entity

Hamadan university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1828 0247

###### Email address

##### Scientific title

Comparison of Preterm Labor Rate in using Proloton and Vaginal Suppository Progesterone in High Risk Pregnancies

##### Public title

Comparison of two drugs for Preterm Labor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: all high risk women for pre-term labour including: recurrent abortion, pre tem labour history, cervical ripening, etc. Exclusion criteria: Epileptic and asthmatic subjects; those with uncontrolled diabetes; those who were sensitive to progesterone; those who have received progesterone four weeks before the study; mental illness; chronic HTN; active liver disorder; HIV infection or 35> CD4 count and anti-viral drug recipients; placenta previa; history of genital and breast cancer; history of thromboembolic disease and mullerian anomaly; ultrasound diagnosed major anomaly; recognized fetal chromosomal abnormalities; Multiple cerclage and preterm labor and PROM and clinical chorioamnionitis; vaginal bleeding and history of

spontaneous preterm labor without delivery (including preterm labor).

#### Age

From **18 years** old to **42 years** old

#### Gender

Female

#### Phase

2

#### Groups that have been masked

No information

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Hamadan university of medical sciences

###### Street address

Daneshgah cross road

###### City

Hamadan

###### Postal code

24118/9/35/16/پ

##### Approval date

2010-05-11, 1389/02/21

##### Ethics committee reference number

16/35/9/24118/پ

### Health conditions studied

#### 1

##### Description of health condition studied

preterm labor

##### ICD-10 code

O60

##### ICD-10 code description

Preterm labour and delivery

### Primary outcomes

#### 1

##### Description

preterm labor

##### Timepoint

monthly

##### Method of measurement

questionnaire and physical exam

### Secondary outcomes

#### 1

##### Description

delivery type

##### Timepoint

monthly

##### Method of measurement

questionnaire

### Intervention groups

#### 1

##### Description

Intervention: 17- $\alpha$ -OH-p (proluton), IM, weekly

##### Category

Treatment - Drugs

#### 2

##### Description

Control: vaginal suppository of progesterone, 100mg, daily

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Fatemie hospital

###### Full name of responsible person

###### Street address

###### City

Hamadan

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Hamadan university of medical sciences

###### Full name of responsible person

Dr. Heidar Tavailani

###### Street address

Hamadan university of medical sciences

###### City

Hamadan

##### Grant name

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamadan university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Hamadan university of medical sciences

**Full name of responsible person**

Mehrangiz Zamani

**Position**

assistance

**Other areas of specialty/work****Street address**

Hamadan university of medical sciences

**City**

Hamadan

**Postal code****Phone**

+98 918 811 2098

**Fax****Email**

m.zamani@umsha.ac.ir

**Web page address****Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Hamadan university of medical sciences

**Full name of responsible person**

Zahara Sabokru

**Position**

resident

**Other areas of specialty/work****Street address**

Hamadan university of medical sciences

**City**

Hamadan

**Postal code****Phone**

+98 912 362 8671

**Fax****Email**

z.sabokro@umsha.ac.ir

**Web page address****Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty